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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/687,848

10/17/2003

Richard S. Ginn

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/02/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/687,848 | Applicant(s) GINN, RICHARD S. | |
| | Examiner MELANIE TYSON | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9, and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 April 2011 has been entered. Claims 2, 4, 6, 8, 10, and 12 remain cancelled. Claims 5 and 7 remain withdrawn from consideration.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 9, and 11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn et al. (U.S. Pub. No. 2002/0077656 A1) and Belhe et al. (U.S. Pub. No. 2004/0215232 A1).

Ginn discloses a locator device (see entire document) comprising an elongate member (312), wherein the distal region has a substantially uniform diameter (for example, see Figures 6A and 6B), and a bioabsorbable occlusion member (320; for example, see paragraph 44) releasably attached by an attachment (336) to a specific position on the elongate member (the distal position; for example, see Figures 6A and 6B), wherein the device and its components are capable of performing the functions claimed. Ginn discloses the elongate member comprises a lumen in contact with the occlusion member (for example, see Figures 6A in 6B in which the lumen of the elongate member is in communication with the interior 332 of the occlusion member), but fails to disclose a distal opening and a proximal opening connected by the lumen, wherein the occlusion member is located distally of the distal opening such that blood can enter the distal opening, flow through the lumen, and exit the proximal opening without passing through the occlusion member.

Belhe discloses a locator device comprising an elongate member (10) for locating a blood vessel and delivering an occlusion member (see entire document). Belhe teaches providing the elongate member with distal (18) and proximal (20) openings connected by the lumen of the elongate member such that blood may pass therebetween to provide the operator with visual feedback as to the position of the

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elongate member (blood flow indicates the elongate member is within the vessel or artery and lack of blood flow indicates the elongate member is outside of the blood vessel or artery; for example, see paragraph 35). Therefore, to provide Ginn's elongate member with proximal and distal openings as taught Belhe would have been obvious to one having ordinary skill in the art at the time the invention was made. Doing so would provide visual feedback to the operator as to the location of the device, thus ensuring proper positioning of the occlusion member. Ginn's occlusion member is located on the distal end of the distal portion of the elongate member and Belhe teaches providing the distal opening proximal of the distal end on the distal portion of the elongate member. These teachings yield the occlusion member located distally of the distal opening. Furthermore, to provide the occlusion member distal of the distal opening would have been obvious to one having ordinary skill in the art at the time the invention was made to ensure the occlusion member does not interfere with the distal opening prior to and/or during deployment of the occlusion member.

Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn et al. and Belhe et al. as applied to claims 1 and 9 above, and further in view of Kensey (U.S. Patent No. 5,061,274). Ginn as modified by Belhe discloses the claimed invention except for the occlusion member being expandable. Kensey also discloses a bioabsorbable occlusion member for sealing an opening (see entire document). Kensey teaches the bioabsorbable occlusion member may be formed of an expandable material so that upon contact with surrounding fluid, the occlusion member expands to engage surrounding tissue and further enhance the seal. To provide Ginn's

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modified device with an expandable occlusion member would have been obvious to one having ordinary skill in the art at the time the invention was made. Doing so would further enhance the seal between the occlusion member and the surrounding tissue, Thus reducing the risk of leaks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose e-mail address is melanie.tyson@uspto.gov and telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Melanie Tyson/
Primary Examiner, Art Unit 3773
May 31, 2011